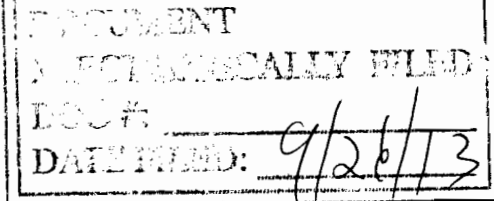


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



-----X
In re: : 11 MDL 2241 (JSR)
FENOFIBRATE PATENT LITIGATION :
: OPINION
-----X

JED S. RAKOFF, U.S.D.J.

While otherwise closing this case, this Court retained jurisdiction to determine whether it had been lied to by a representative of plaintiff Lupin Atlantis Holdings S.A. ("Lupin"). While deeply troubled by Lupin's conduct, the Court concludes in the end that no further action is warranted.

In the underlying multi-district litigation, Lupin, the owner of the approved New Drug Application for the prescription drug Antara and the licensee of two associated U.S. patents, asserted claims that defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") infringed these patents by seeking federal regulatory approval to manufacture a generic version of Antara. Following considerable motion practice, this Court granted summary judgment to Mylan on December 27, 2012. The next day, Lupin filed an emergency motion for an injunction pending appeal to prevent Mylan from bringing its generic drug to market. In connection with that motion, Lupin submitted a sealed declaration from Michael Proctor, Senior Vice President of Sales and Marketing for Lupin's brand business. That declaration, a redacted version of

which the Court has now unsealed, contained two paragraphs relevant here:

15. As an initial matter, the U.S. sales of Antara total \$45 million. We have projected that 80% of Antara sales will be lost by the brand business if a generic is launched.

16. The loss of revenue will require downsizing of sales representatives, support staff, and managers within Lupin's brand business. We have estimated that the size of such downsizing will be 60% of the total brand marketing force. Over 100 people, all within the United States, will lose their jobs.

Decl. of Michael Proctor ("Proctor Decl.") ¶¶ 15-16. These paragraphs provided the basis for Lupin's primary argument as to why it would suffer irreparable harm in the absence of an injunction.

Notwithstanding Proctor's declaration, this Court denied Lupin's motion on January 4, 2013. On January 7, 2013, however, Lupin filed a similar motion for an injunction pending appeal with the Federal Circuit, submitting the same sealed declaration from Proctor. The Federal Circuit granted Lupin's motion on February 11, 2013.

On February 14, 2013, however, Mylan learned of certain statements by Lupin's CEO, Vinita Gupta -- made to investors during a regular public earnings call -- that were inconsistent with Proctor's declaration. In particular, in the context of a discussion of the impact Mylan's threatened generic launch might have on Antara and Lupin, an analyst pointed out that Lupin had

significantly expanded its sales force when it acquired Antara, and asked whether the company could "persist with the same enlarged team only with Suprax" -- that is, without Antara. Decl. of Natalie Clayton ("Clayton Decl."), ex. 3, at 22. Ms. Gupta responded: "Absolutely. It's still very profitable even without Antara." Id.

After Mylan raised this inconsistency, Lupin, on February 15, 2013, submitted a supplemental sealed declaration from Proctor attempting to explain the discrepancy. Proctor stated that he had reviewed Ms. Gupta's comments, and explained that "[i]n my view, Ms. Gupta was viewing the market in a forward-looking manner, where she took into account the possibility of Lupin acquiring additional brand products in the future," thus mitigating the losses Proctor anticipated from generic competition to Antara. Suppl. Decl. of Michael Proctor ¶ 7, ex. 3 to Clayton Decl. Proctor also observed that Ms. Gupta's statements "were made in the context of the investor call, during which [her] projections were subject to the Safe Harbor disclaimer language found on page 29 of the transcript." Id. Proctor concluded: "[I]f there is a generic launch of Antara, and if Lupin does not acquire additional brands that are capable of mitigating the loss of revenue caused by the generic launch of Antara and supporting Lupin's current sales force, then, in my view, Lupin will need to downsize and reduce its total brand

marketing force, which I have estimated to be a reduction of 60%." Id. ¶ 8.

On February 22, 2013, the Federal Circuit dissolved its previously issued injunction pending appeal. On February 28, 2013, the Federal Circuit summarily affirmed this Court's decision on summary judgment. Lupin did not seek further appellate relief, and the mandate issued on April 8, 2013.

On May 24, 2013, Mylan filed a motion with the Court to recover damages resulting from Lupin's having obtained, allegedly by manipulation, the Federal Circuit's injunction pending appeal. In its moving papers, Mylan for the first time brought to this Court's attention the possibility that Proctor's declaration might have contained a material misrepresentation. At the oral argument on Mylan's motion, the Court accordingly scheduled an evidentiary hearing "to determine whether an intentional lie was presented to this Court and/or to the Federal Circuit." Tr. of Sept. 6, 2013, at 2. Shortly before the hearing, Mylan and Lupin resolved the pending matter. The Court, however, faced with a plausible contention that it had been lied to, ordered the hearing to proceed.

At the hearing, Proctor initially testified about his position at Lupin and confessed that he had signed the declaration in question and that he had read the declaration and conferred with Lupin's counsel before doing so. Tr. of Aug. 21,

2013, at 6-9. Beyond that, however, Proctor refused to answer any further questions, invoking his Fifth Amendment right against self-incrimination. Id. at 9-11.

Gupta also testified, without limitation. When asked by the Court if she agreed with the statement in Proctor's declaration to the effect that, in the absence of an injunction, a hundred people "will lose their jobs," Gupta refused to disavow the statement, but explained that she "would have worded it differently." Id. at 17. In particular, she would have stated that "up to a hundred people within the United States risk losing their jobs." Id. (emphasis added). When asked if it was fair to say that she painted a very different picture on the earnings call, Gupta explained that her answer to the analyst focused on the "profitability of the brand business," and sidestepped the question of downsizing, id. at 18, about which the company had not yet made any decisions, id. at 21.

Gupta acknowledged, however, that at the time of Proctor's declaration, she was not aware of anyone in the company having prepared an estimate of the market share Lupin expected Antara to cede to a generic competitor, nor of any estimate of the size of any downsizing that might result. Id. at 22-24. Gupta nevertheless testified that she believed Proctor's projections of an 80% loss of market share and downsizing of 100 U.S. employees were reasonable back-of-the-envelope estimates. With

respect to market share, Gupta stated that based on Lupin's experience with generic drugs, "we know . . . that when a brand loses patent exclusivity, 80 to 90 percent of the product goes generic." Id. at 22. And with respect to downsizing, Gupta noted that when Lupin acquired the rights to Antara, it added 100 employees to market the drug, and therefore it would be reasonable to assume that "up to a hundred" people could lose their jobs if Antara were to go generic. Id. at 17. Gupta added, however, that at the time of Proctor's declaration, Lupin was "working on a commercial strategy on Antara to be able to life-cycle manage the product," id. at 24, which could reduce anticipated revenue losses and the attendant need for downsizing.

When asked how many people had in fact lost their jobs since the Federal Circuit's affirmance of this Court's summary judgment decision, Gupta answered, "I believe it's 12." Id. at 21. In a post-hearing declaration, however, Gupta clarified that "while employees of the brand business were terminated or otherwise left [Lupin] during the period and [Lupin] closed nine territories partly due to the launch of a generic form of Antara®, no employees were terminated due to a loss of revenue relating to the availability of a generic form of the drug." Decl. of Vinita Gupta ¶ 2.

Having considered all the testimony presented at the hearing, as well as the post-hearing letter brief submitted by Proctor's counsel, the Court has little difficulty finding that Proctor's declaration materially overstated the risk of job losses that would result from generic competition to Antara. While Proctor may have had a reasonable basis to declare, as Gupta suggested, that "up to a hundred people within the United States risk losing their jobs," he had no adequate basis to state, definitively, that "over 100 people, all within the United States, will lose their jobs."

This distinction is not a mere matter of semantics. As any minimally sophisticated party seeking preliminary injunctive relief should be aware, the Supreme Court has held that such relief cannot be granted absent a showing that irreparable harm is "likely," rather than a mere "possibility." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 22 (2008). Had Proctor been more accurate, Mylan would have been able to probe this issue more closely, aiding this Court and the Federal Circuit in the proper resolution of Lupin's motions. Moreover, because Proctor's declaration was submitted in connection with an emergency motion, Mylan, this Court, and the Federal Circuit had no opportunity to question Proctor further about this issue in a deposition or on the witness stand. The instant issue thus highlights the ways in which courts resolving motions for

preliminary relief, especially on an emergency basis, are more heavily reliant than usual on the parties' good faith. That reliance should, in contrast to Proctor's carelessness, lead parties to be especially vigilant about the factual representations they make.

The Court is also disturbed by the fact that Lupin shamelessly adopted contrary positions depending on who it was testifying to, allowing a senior executive to tell two different federal courts -- in a sealed declaration inaccessible to the public, no less -- that generic competition would cause major revenue and job losses, while allowing the CEO to effectively tell investors in a contemporaneous public earnings call that nothing of the sort would occur. Such fecklessness threatens the public's confidence in both the truth-seeking function of the judicial system and the integrity of our business leaders.

Nevertheless, beyond bringing these facts to light, the Court declines to take any further action in this matter. Although Proctor was at least negligent in how he worded his declaration (or allowed it to be worded by Lupin's attorneys), the Court cannot conclude that he did not have at least some good-faith basis for his statements. Accordingly, such actions as the Court originally contemplated, such as referral to the Department of Justice for possible perjury prosecution, appear unwarranted.

Dated: New York, New York
September ~~25~~, 2013


JED S. RAKOFF, U.S.D.J.